

510(k) SUMMARY

K962289

June 6, 1996

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a 510(k) Summary for the Intermedics Orthopedics, Inc. Select® Shoulder System CoCr Humeral Stem.

Submitter: Intermedics Orthopedics, Inc.
9900 Spectrum Drive
Austin, TX 78717
(512) 432-9900

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis - 21 CFR 888.3690

Common/Usual Name: Humeral Stem

Trade/Proprietary: Select® Shoulder CoCr Humeral Stem

Product Description/Substantial Equivalence:

The Select Shoulder Humeral Stem is a metallic humeral component manufactured from cobalt chrome alloy (CoCrMo) and is intended for use either with or without bone cement in hemiarthroplasty. The humeral stem is available in a variety of sizes and lengths and features a proximally grit blasted surface (except for the head stem taper) for biologic or cement fixation. The proximal trapezoidal shape tapers in the A-P plane, thus providing for a stable cement mantle. The proximal body also features an antirotation fin on the lateral aspect. Suture holes are provided in the medial proximal body and lateral fin to allow for soft tissue/bony fragment attachment and tensioning, thus resulting in a more biomechanically stable construct for repair of proximal humeral fractures. A male IOI morse type taper permits attachment of one of the metallic humeral heads offered by Intermedics Orthopedics. This taper is identical to the taper of the previously cleared Select Shoulder System. Distally, the stem is rounded and fluted to provide enhanced fixation and rotational stability. The distal stem tip is designed to accept a cement centralizer. The humeral stem is designed for use with Intermedics Orthopedics humeral heads in a variety of sizes and heights for increased stability of the glenohumeral joint.

Fatigue analysis and taper testing of the Select Shoulder Humeral Stem indicated that the device would survive physiologic loading.

The Select Shoulder CoCr Humeral Stem is similar to those of the Depuy Global Total Shoulder System, the Biomet Bio-Modular Total Shoulder, the Zimmer Fenlin Total Shoulder, the Kirschner Integrated Shoulder System, the 3M/Orthomet Neer II Shoulder System, and the Smith & Nephew Richards Cofield Shoulder.